

TITLE: Respiratory Precautions for Protection from Bioaerosols or Infectious Agents: A

**Review of the Clinical Effectiveness and Guidelines** 

**DATE:** 19 August 2014

### **CONTEXT AND POLICY ISSUES**

There are a number of infectious diseases that are transmitted from person to person via the respiratory route, including influenza, tuberculosis (TB), and severe acute respiratory syndrome (SARS) coronavirus, and these infectious agents are associated with considerable morbidity and mortality. Healthcare workers (HCWs) are vulnerable to exposure to these agents given the nature of their jobs, and as a result, risk both becoming infected, and spreading the infectious agents to other patients. To avoid transmission of these infectious diseases to (HCWs), exposure-appropriate respiratory precautions are sometimes necessary to protect both HCWs and the patients they care for. However, the selection of respiratory equipment depends on the pathogen, aerosol generation rate, and ventilation rate.

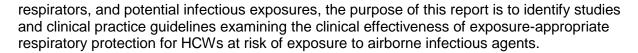
Two types of devices that are commonly used to prevent transmission of airborne infectious agents are medical masks and respirators. For this report, medical masks (also known as surgical masks or surgical face masks) are defined as unfitted devices worn by the healthcare worker (HCW) "to reduce transfer of potentially infectious bodily fluids between individuals". Masks are designed prevent droplets from an infectious patient from coming in contact with the mucous membranes in the nose and mouth of the person wearing the mask. It must be noted that masks are not designed to filter small airborne infectious particles. In contrast, respirators are "medical devices designed to protect the wearer from airborne infectious aerosols transmitted directly from the patient or when artificially created such as during aerosol-generating procedures", and this is done by filtering the airborne particles (known as an airpurifying respirator) or supplying clean air to the person wearing the respirator (known as an atmosphere-supplying respirator). Air-purifying respirators are further classified by the efficiency at which they remove particles (95%, 99%, and 100%), and into N-Series respirators that are not resistant to oil (N95, N99, N100), R-Series that are resistant to oil (R95, R99, R100), and P-Series that are oil-proof (P95, P99, P100).

As the Canadian Biosafety Standards and Guidelines note: "Using the wrong respirator or misusing one can be as dangerous as not using one at all". 5 Given the variety of devices,

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#### **RESEARCH QUESTIONS**

- 1. What is the clinical effectiveness of exposure-appropriate respiratory protection for healthcare workers at risk of exposure to bioaerosols or infectious agents?
- 2. What is the comparative clinical effectiveness of different types of respiratory protection for healthcare workers at risk of exposure to bioaerosols or infectious agents?
- 3. What are the evidence-based guidelines regarding the selection of respiratory protection for healthcare workers at risk of exposure to bioaerosols or infectious agents?

### **KEY MESSAGE**

Evidence and recommendations for respiratory protection varies based on the type of infectious agent. N95 respirators were found to be more effective at preventing viral infection and bacterial colonization in HCWs relative to medical masks. Guidelines were consistent in recommending at least an N95 respirator for care of patients with TB (low and high risk situations) and SARS (high risk situations), and medical masks for seasonal influenza in low risk situations, but were inconsistent for SARS in low risk situations, as well as pandemic influenza in low risk situations, and seasonal influenza in high risk situations.

### **METHODS**

### **Literature Search Strategy**

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014, Issue 7), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. Methodological filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, non-randomized studies, and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2003 and July 21, 2014.

#### **Selection Criteria and Methods**

One reviewer screened the titles and abstracts of the identified publications for relevancy, and evaluated the applicable full-text publications for inclusion in this report based on the criteria listed in table 1.



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Population	Q1, Q2 and Q3: Adults working in healthcare environments in which	
	they are at risk of exposure to bioaerosols or infectious agents	
Intervention	Q1, Q2 and Q3: Respiratory equipment	
Comparator	Q1, Q3: No respirator	
	Q2, Q3: Different respirators compared to one another	
Outcomes	Q1, Q2: Clinical effectiveness (e.g. infection, contamination,	
	colonization, or other adverse events)	
	Q3: Guidelines	
Study Designs	Q1, Q2: Health technology assessments, systematic reviews, meta-	
	analyses, randomized controlled trials, non-randomized studies	
	Q3: Clinical practice guidelines	

#### **Exclusion Criteria**

Studies were excluded if they did not meet the selection criteria, if they were duplicate publications, if they were simulation studies, or were published prior to January 1, 2003.

### **Critical Appraisal of Individual Studies**

Systematic reviews and meta-analyses were critically appraised using the AMSTAR instrument. Randomized controlled trials were appraised using the Downs and Black Checklist. Clinical practice guidelines were critically appraised using the AGREE II Instrument. Numeric scores were not calculated for the included studies or guidelines. Instead, a review of the strengths and limitations of each included study and guideline were described narratively.

### **SUMMARY OF EVIDENCE**

### **Quantity of Research Available**

The literature search identified 222 citations, with an additional 46 citations identified from the grey literature. After screening of the abstracts, 63 potentially relevant studies were identified for full-text review. After full text review, a total of 8 studies were included in this review.

The PRISMA flowchart in Appendix 1 provides the details of the study selection process.<sup>10</sup>

### **Summary of Study Characteristics**

Details on study design, critical appraisal, and study findings are located in Appendices 2, 3, and 4, respectively.

### Study Design

Among the included studies, there was one systematic review of studies,<sup>11</sup> two randomized controlled trials,<sup>4,12</sup> four clinical practice guidelines,<sup>1,13-15</sup> and one systematic review of clinical practice guidelines.<sup>3</sup> The systematic review included studies of any design, and studies included in the review were published from 1981 to 2006.<sup>11</sup> The systematic review of clinical practice guidelines included a total of 27 guidelines.<sup>3</sup>

### Country of Origin

The two randomized controlled trials were conducted on HCWs in China. 4.12 The systematic review originated in Australia, 11 and the clinical practice guidelines were from the United Kingdom, 1 the United States, 13,15 and the World Health Organization (WHO), 14 and the systematic review of clinical practice guidelines originated from Australia and included guidelines from the WHO, Canada, the United States, the United Kingdom, Australia, China, India, Indonesia, Pakistan, Bangladesh and Vietnam. 3

### Study Population

Study populations in the randomized controlled trials were hospital-based, and involved HCWs caring for patients in emergency departments and respiratory units.<sup>4,12</sup> The systematic review of studies did not provide details regarding the areas of practice of the HCWs included in the review.<sup>11</sup>

### Interventions and Comparators

Interventions identified in the available studies included medical masks, <sup>11</sup> N95 respirators (both fit-tested and non-fit-tested, and continuous use and targeted use). <sup>4,11,12</sup> The comparators in the cluster randomized trials were medical masks and no masks. <sup>4,12</sup> The clinical practice guidelines evaluated available literature on respiratory protection, including medical masks and different types of respirators. <sup>1,13-15</sup>

#### Clinical Outcomes

Clinical outcomes included development of infection, including SARS, respiratory syncytial virus (RSV), *Bordatella pertussis*, bacterial colonization, percent efficacy against bacterial and viral infection development, and bacterial colonization.<sup>4,11,12</sup>

One clinical practice guideline reported how evidence was graded and what evidence was used to formulate the respective recommendations.<sup>15</sup> Evidence within this guideline was classified using the following information<sup>15</sup>:

- Category IA: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
- Category IB: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.
- Category IC: Required for implementation, as mandated by federal and/or state regulation or standard.
- Category II: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.
- No recommendation: unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.

Of note, the systematic review of clinical practice guidelines did not evaluate the quality of the guidelines that were included in the review.<sup>3</sup>

## **Summary of Critical Appraisal**

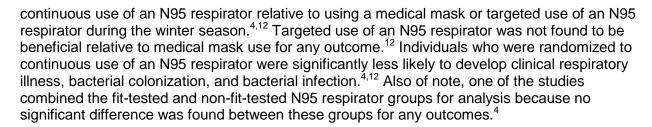
The systematic reviews included in this report both clearly described the objectives of the review and the databases that were searched to find relevant literature. One review searched two databases (Medline and Pubmed), whereas the systematic review on clinical practice guidelines searched Medline, Embase, National Guidelines Clearinghouse, Google Scholar, and websites of relevant organizations, and contacted individuals in government to identify applicable guidelines. One review included publications in all languages, whereas the other only included English publications. Independent duplicate study inclusion assessment and data extraction were not performed in either review. Only one review assessed the quality of the included studies and considered the quality when drawing conclusions from the results. Neither systematic review reported on excluded studies, nor did they assess the possibility of publication bias.

In terms of the two RCTs included, both were from the same study author group (although different study population), and the quality of the studies was comparable. For the study conducted in 2013, a sample size calculation was not reported in the manuscript, nor was the process for randomizing hospital clusters. 12 In comparison, the process for randomization was discussed in the 2014 study, and authors used a computerized randomization program to randomize participating hospitals to one of the three intervention arms. In addition, it was unclear whether the hospitals used in the control population were of a different patient acuity (severity of illness) from the hospitals randomized to the interventions. 12 Recognizing that adherence to use of medical masks and respirators (for example, lack of use in the continuous use groups or respirator use in the mask group, for example) may impact study results, participants in both studies were required to keep a daily diary on mask and/or respirator usage. 4.12 Lastly, study assessors were not blinded to the intervention received by each study participant, although study authors did attempt to minimize the identification of interventions among study participants by using a cluster randomized controlled study design, that is, randomizing hospital sites to an intervention instead of randomizing individuals to an intervention. 4,12

Based on the AGREE II instrument, the four guidelines included in this report were of relatively poor quality. While all of the guidelines specified their objectives and target audiences, none of the included guidelines reported the methods for developing recommendations, nor did then discuss whether the guidelines had undergone external review prior to release. Two guidelines mentioned how evidence was identified from the literature to inform the guidelines. In addition, three of the guidelines did not provide a link between the recommendations and the evidence used to develop those recommendations.

### **Summary of Findings**

Inconsistent results were found in the systematic review evaluating studies on respiratory protection. This could be due to the quality of evidence that was identified during the literature search, with the highest quality studies being observational in nature (one cohort study and five case-control studies). Among the highest quality studies, three of the six studies found wearing a mask or respirator protective against SARS or RSV, and the other three studies found that wearing a mask or respirator was not protective. Of note, these studies were limited by small sample sizes that limited power to detect a difference between groups. Also, compliance to mask or N95 respirator use was difficult to measure retrospectively, further limiting conclusions. In contrast, both cluster RCTs demonstrated a protective benefit associated with



In terms of clinical practice guidelines, recommendations were similar across guidelines for managing patients with TB (N95 respirator or equivalent), as well as low risk seasonal influenza (medical mask), SARS high risk (N95 respirator or equivalent), high risk pandemic influenza (N95 respirator or equivalent) and with most infectious patients undergoing aerosol-generating procedures (N95 respirator or equivalent). Recommendations differed, however, for low risk pandemic influenza and high risk seasonal influenza. For example, guidelines from Canada and Vietnam recommended a medical mask for use in high risk seasonal influenza situations, whereas other guidelines recommended the use of an N95 respirator.

#### Limitations

Most available studies included in the systematic review and clinical practice guidelines were of poor methodological quality, thereby limiting conclusions that can be drawn from the results. In addition, the cluster randomized trials were conducted in China, and may not be applicable in Canada if infection prevention and control measures differ between countries, for example. Also, the cluster randomized trials assessed the outcome of bacterial colonization, and it is unclear whether this outcome is clinically relevant. Also, guideline recommendations differed in some situations, including high risk seasonal influenza and low risk pandemic influenza, which also may reflect the relatively poor quality of currently available studies. Another limitation is the relatively small number of pathogens that were evaluated in the identified literature. Lastly, there were no studies identified for this report that compared different types of respirators, limiting the conclusions to the specific N95 respirators examined in the included studies.

### CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Recommendations for type of respiratory protection varied based on pathogens. It appears that continuous use of N95 respirators are more effective than medical masks and targeted N95 respirator use for reducing bacterial colonization and bacterial infection, as well as clinical respiratory infection, for HCWs during winter months. According to clinical practice guidelines: patients with an infectious disease that is spread through the respiratory tract, HCWs should wear an N95 respirator when performing necessary aerosol-generating procedures, as well as when managing patients with TB, high risk situations in hose with SARS, and in situations where high risk pandemic influenza exists. For managing patient situations with low risk seasonal influenza, a medical mask is recommended.

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### **APPENDIX 1: Selection of Included Studies**

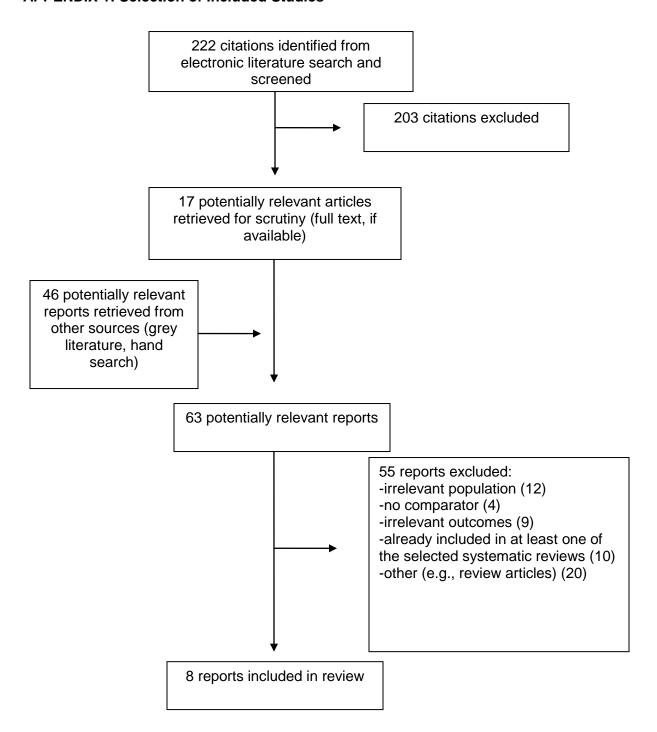




Table 2.1 Characteristics of Included Studies

		cluded Studies Patient	Intervention	Comparator(a)	Clinical
First Author, Publication	Study		intervention	Comparator(s)	
	Design,	Characteristics,			Outcomes
Year, Country	Length of Follow-up	Sample Size (n)			
Systematic Rev					
Gralton, 2010,	Systemati	Study sample	N95	Medical mask	• Dovolonment
Australia <sup>11</sup>	c review of			(versus N95	Development     SABS
Australia	21	sizes ranged from 1 person to	respirator	`	of SARS
	observatio	2298 patient	Medical	respirator)	Severity of
	nal studies	admissions	mask	No mask	SARS
	(1 cohort	aumissions	IIIask	INO IIIASK	Development
	study, 2	Exposures			of RSV
	time	included SARS			Development
	series	contacts (17			of Bordatella
	studies, 5	studies), RSV			Pertussis
	case	contacts (3			infection
	control	studies), and			
	studies, 4	Bordatella			
	cross-	Pertussis			
	sectional	contacts (1			
	studies, 9	study)			
	case	olddy)			
	series or				
	case				
	report)				
	Τοροιί				
	Years of				
	publication				
	: 1981 -				
	2006				
Randomized Co		als	<u> </u>	<u> </u>	<u>I</u>
MacIntyre,	Cluster	HCWs included	3M flat-fold	3M	Bacterial
2014, China <sup>4</sup>	randomize	nurses and	N95	Medical masks	colonization
,	d trial	doctors who	respirator (fit	(n = unclear)	• Percent
		worked full time	and non-fit-	,	efficacy
	Study time	in emergency	tested)	Control HCWs	against co-
	frame:	departments or	(n = unclear)	who did not	infection with
	December	respiratory	,	routinely wear	two bacteria
	1, 2008 –	wards at 24		masks (n = 481)	or a virus and
	January	hospitals		,	bacteria
	15, 2009				<ul> <li>Percent</li> </ul>
		n = 1,441			efficacy
		randomized to			against
		either a fit-tested			Infections
		N95 respirator, a			with bacteria
		non-fit-tested			or viruses

First Author, Publication Year, Country	Study Design, Length of Follow-up	Patient Characteristics, Sample Size (n)	Intervention	Comparator(s)	Clinical Outcomes
Maclatina	Chroton	N95 respirator, or a medical mask	ONAL Locks	Torreste d NOS	Dringer
MacIntyre, 2013, China <sup>12</sup>	Cluster randomize d trial  Study time frame: December 28, 2009 – February 7, 2010	HCWs included nurses and doctors working on emergency departments or respiratory wards of 19 hospitals	3M Health Care N95 Particulate Respirator (n = 581)	Targeted N95 respirator (for high risk procedures only) (n = 516)  3M Standard Tie-On Surgical Mask (n = 572)	Primary endpoints:  Clinical respiratory illness (defined as two or more respiratory symptoms or one respiratory symptom and one systemic symptom) Influenza-like illness (defined as a fever 38 degrees or more plus one respiratory symptom) Laboratory- confirmed viral respiratory infection in symptomatic subjects (adenoviruses , human meta- pneumovirus, coronaviruses , parainfluenza viruses, RSV, or rhinoviruses) Laboratory- confirmed influenza A or

First Author, Publication Year, Country	Study Design, Length of Follow-up	Patient Characteristics, Sample Size (n)	Intervention	Comparator(s)	Clinical Outcomes
					B in symptomatic subjects  • Laboratory-confirmed bacterial colonization in symptomatic subjects (Streptococcu s Pneumonaie, Bordatella pertussis, Mycoplasma pneumonia, Haemophilus influenza type B, legionella, or chlamydia)

HCW: healthcare worker; RSV: respiratory syncytial virus; SARS: severe acute respiratory syndrome

**Table 2.2 Characteristics of Included Guidelines** 

Author, Year, Origin	Objective of Guideline	Evidence Collection, Selection and Synthesis
Systematic Re	eview of Clinical Practice Guidelines	
Chugati, 2013, Australia <sup>3</sup>	To examine available policies and guidelines around the use of masks and respirators for HCW, for the prevention of influenza, SARS, and TB     To describe areas of consistency/inconsistency between guidelines with reference to the WHO and the CDC guidelines	<ul> <li>Literature searched using Medline, Embase, National Guidelines Clearinghouse, and Google Scholar</li> <li>Personal contacts in selected countries were also contacted regarding availability of guidelines in that country</li> <li>Predefined criteria were used to identify included guidelines, and search results were assessed by one individual, and validated by two other individuals</li> <li>Guidelines were described by country/organization, department, publication year, language and recommendations on mask/respirator use</li> </ul>

Author, Year, Origin	Objective of Guideline	Evidence Collection, Selection and Synthesis
CDC, 2013, United States <sup>13</sup> Coia, 2013, United Kingdom <sup>1</sup>	To update previous CDC guidance on seasonal and H1N1 influenza based on newly published evidence  To provide best practice guidelines for HCWs to select the appropriate respiratory and facial protection to minimize the risk of acquisition of infection in the workplace	<ul> <li>Unclear how evidence was collected, selected, or synthesized for guideline – this was not reported</li> <li>Evidence formulating the guidelines was collected in a separately published literature review<sup>6</sup></li> <li>Selection of the evidence was not reported</li> <li>Synthesis of the evidence was based on expert consensus</li> </ul>
Siegel, 2007, United States <sup>15</sup>	Objectives:  1) provide infection control recommendations for all components of the healthcare delivery system, including hospitals, long-term care facilities, ambulatory care, home care and hospice;  2) reaffirm Standard Precautions as the foundation for preventing transmission during patient care in all healthcare settings;  3) reaffirm the importance of implementing Transmission-Based Precautions based on the clinical presentation or syndrome and likely pathogens until the infectious etiology has been determined; and  4) provide epidemiologically sound and, whenever possible, evidence-based recommendations.	<ul> <li>Medline and Pubmed used to identify English language studies from 1996</li> <li>Unclear how evidence was selected for inclusion in the guideline</li> <li>Evidence synthesis: each recommendation was categorized on the basis of existing scientific data, theoretical rationale, applicability, and when possible, economic impact:</li> <li>Category IA: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.</li> <li>Category IB: Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies and a strong theoretical rationale.</li> <li>Category IC: Required for implementation, as mandated by federal and/or state regulation or standard.</li> <li>Category II: Suggested for implementation and supported by suggestive clinical or epidemiologic studies or a theoretical rationale.</li> <li>No recommendation: unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.</li> </ul>

Author, Year, Origin	Objective of Guideline	Evidence Collection, Selection and Synthesis
WHO, 2006 <sup>14</sup>	To provide consistent, up-to-date recommendations on the diagnosis and management of drug-resistant TB, applicable to a variety of geographical, political, economic and social settings	Unclear how evidence for development of the guideline was collected, selected, or synthesized – this was not reported

CDC: Centers for Disease Control; HCW: healthcare worker; SARS: severe acute respiratory syndrome; TB: tuberculosis; WHO: World Health Organization



**APPENDIX 3: Critical Appraisal of Individual Studies** 

**Table 3.1: Critical Appraisal of Included Clinical Studies** 

First	Strengths	Limitations
Author,		
Publication		
Year,		
Country		
Systematic F		<u></u>
Gralton, 2010, Australia <sup>11</sup>	<ul> <li>The objectives of the review were clearly described</li> <li>Databases searched were clearly specified</li> <li>Both study authors assessed search results for relevance</li> <li>Study quality was assessed using the Designations of Evidence from the National Health and Medical Research Council</li> <li>Characteristics of the included studies were provided</li> <li>Conflict of interest statement</li> </ul>	<ul> <li>Studies were restricted to English language</li> <li>Grey literature was not searched</li> <li>Unclear whether both study authors assessed relevant studies for inclusion</li> <li>Unclear how data extraction was performed</li> <li>No report of how many studies were excluded</li> <li>The likelihood of publication bias was not assessed</li> </ul>
Randomized	was included    Controlled Trials	
MacIntyre, 2014, China <sup>4</sup>	<ul> <li>The aim of the study was clearly descried</li> <li>A cluster randomized trial design was used to avoid disclosure of interventions</li> <li>The interventions were clearly described</li> <li>Study outcomes were clearly described, and possibility of outcomes was assessed in study participants on a daily basis</li> <li>Study investigators attempted to evaluate adherence to respirator or mask by requiring HCWs to keep diaries on use</li> <li>Participants were representative of the population of interest</li> </ul>	<ul> <li>No sample size calculation performed</li> <li>Characteristics of included study participants was not reported</li> <li>Unclear whether the hospitals that served as the control population had a different acuity of patients relative to the hospitals with participants who received masks or respirators (these individuals were not randomized to the control group)</li> <li>Unclear whether there were losses to follow up</li> <li>Study assessors were not blinded to the intervention</li> </ul>
MacIntyre, 2013, China <sup>12</sup>	The aim of the study was clearly described A cluster randomized trial design was used to avoid disclosure of interventions	Study assessors were not blinded to the intervention

First Author, Publication Year, Country	Strengths	Limitations
	<ul> <li>The interventions were clearly described</li> <li>Study outcomes were clearly described and study participants were assessed on a daily basis</li> <li>Study investigators attempted to evaluate adherence to respirator or mask by requiring HCWs to keep diaries on use</li> <li>Participants were representative of the population of interest</li> <li>Analysis was intention-to-treat</li> <li>A sample size calculation was provided, and sample size was appropriate</li> <li>Characteristics of those included in the study, stratified by intervention received, were provided</li> </ul>	

Table 3.2: Critical Appraisal of Included Guidelines

Table 3.2: Critical Appraisal of included Guidelines			
First	Strengths	Limitations	
Author,			
Publication			
Year,			
Country			
Systematic I	Review of Clinical Practice Guidelines		
Chugati, 2013, Australia <sup>3</sup>	<ul> <li>The objectives of the review are clearly specified</li> <li>Databases searched are clearly specified</li> <li>Included publications in all languages</li> <li>Characteristics of included studies are provided</li> <li>Conflict of interest statements are provided</li> </ul>	<ul> <li>Unclear whether duplicate data extraction was completed</li> <li>Characteristics of excluded studies are not provided</li> <li>Quality assessment of included studies was not completed</li> <li>Possibility of publication bias was not assessed</li> </ul>	
Clinical Practice Guidelines			
CDC, 2013, United States <sup>13</sup>	<ul> <li>The objective of the guideline is clearly specified</li> <li>The health topic is clearly specified</li> <li>The population to which the</li> </ul>	<ul> <li>Does not mention whether the views of the population to which the guideline applies were sought</li> <li>Unclear how evidence to support recommendations within the</li> </ul>	

First Author, Publication Year, Country	Strengths	Limitations
	<ul> <li>guideline applies is clearly mentioned</li> <li>Recommendations are specific and unambiguous</li> <li>Key recommendations are easily identifiable</li> <li>The guideline provides tools for putting recommendations into practice</li> </ul>	<ul> <li>guideline was identified</li> <li>Strengths and limitations of the evidence used to formulate the guideline are not reported</li> <li>Methods for developing the recommendations are not reported</li> <li>Unclear whether there is a link between the evidence available and the recommendations made</li> <li>Unclear if the guideline was externally reviewed prior to release</li> <li>A procedure for updating the guideline was not specified</li> <li>Competing interests of guideline authors are not reported</li> </ul>
Coia, 2013, United Kingdom <sup>1</sup>	<ul> <li>The overall aim of the guideline is clearly described</li> <li>The health topic is clearly specified</li> <li>The population to which the guideline applies is clearly mentioned</li> <li>Guideline includes authors from relevant professional groups</li> <li>Recommendations are specific and unambiguous</li> <li>Key recommendations are easily identifiable</li> <li>The guideline provides tools for putting recommendations into practice</li> <li>Competing interests of guideline authors are reported</li> </ul>	<ul> <li>Methods for developing the recommendations are not reported</li> <li>Unclear whether there is a link between the evidence available and the recommendations made</li> <li>Unclear if the guideline was externally reviewed prior to release</li> <li>A procedure for updating the guideline was not specified</li> </ul>
Siegel, 2007, United States <sup>15</sup>	<ul> <li>The objective of the guideline is clearly specified</li> <li>The health topic is clearly specified</li> <li>The population to which the guideline applies is clearly mentioned</li> <li>Methods for identifying evidence for the guideline are specified</li> <li>Strengths and limitations of the</li> </ul>	<ul> <li>Does not mention whether the views of the population to which the guideline applies were sought</li> <li>Methods for developing the recommendations are not reported</li> <li>Unclear if the guideline was externally reviewed prior to release</li> <li>A procedure for updating the guideline was not specified</li> <li>Competing interests of guideline</li> </ul>

First Author, Publication Year, Country	Strengths	Limitations
	<ul> <li>evidence used to formulate the guideline are reported</li> <li>Recommendations are specific and unambiguous</li> <li>Key recommendations are easily identifiable</li> <li>Recommendations are linked with evidence</li> </ul>	authors are not reported
WHO, 2006 <sup>14</sup>	The objective of the guideline is clearly specified The health topic is clearly specified The population to which the guideline applies is clearly mentioned Recommendations are specific and unambiguous	<ul> <li>Does not mention whether the views of the population to which the guideline applies were sought</li> <li>Unclear how evidence to support recommendations within the guideline was identified</li> <li>Strengths and limitations of the evidence used to formulate the guideline are not reported</li> <li>Methods for developing the recommendations are not reported</li> <li>Unclear whether there is a link between the evidence available and the recommendations made</li> <li>Key recommendations are not easily identifiable</li> <li>Unclear if the guideline was externally reviewed prior to release</li> <li>A procedure for updating the guideline was not specified</li> <li>Competing interests of guideline authors are not reported</li> </ul>

CDC: Centers for Disease Control; WHO: World Health Organization

## **APPENDIX 4: Individual Study Findings**

Table 4.1: Results of Included Studies

First Author, Publication Year	Main Study Findings	Authors' Conclusions
Systematic R Gralton, 2010, Australia <sup>11</sup>	<ul> <li>Evidence for use of masks and respirators was of low quality</li> <li>The highest quality studies were one cohort study (evaluating exposure to RSV) and five case-control studies (evaluating exposure to SARS)</li> <li>Among the seventeen studies evaluating exposure to SARS, medical masks were found to be protective in two studies, not protective in three studies, and not established in four studies, whereas N95 respirators were found to be protective in six studies, not protective in two studies, and not established in five studies (note that some studies evaluated both medical masks and N95 respirators)</li> <li>Comparisons between N95 respirators and medical masks were not reported</li> <li>Among the one study evaluating exposure to Bordatella pertussis, medical masks were found to be protective</li> <li>Among the three studies evaluating exposure to RSV, two studies found that medical masks were protective</li> </ul>	<ul> <li>"This review has found an absence of high-level study designs with conclusive evidence describing the effectiveness of both surgical and N95 mask use in HCW. The highest level of evidence emerged from five case-control studies and one cohort study." – page 664</li> <li>Among the six highest quality evidence studies: "Four of these studies reported mask use alone conferred protective benefit and after reanalysis these claims were upheld for three of these studies." – page 664</li> <li>"World Health Organization guidelines recommend surgical masks for all patient care with the exception of N95 masks for aerosol-generating procedures. Because of the paucity of high-quality studies in the healthcare setting, the current guidelines for the advocacy of certain mask types cannot be supported or nullified given the current evidence." – page 665</li> </ul>

First	Main Study Findings	Authors' Conclusions
Author,		
Publication		
Year		
	Controlled Trials	(0.12-
MacIntyre, 2014, China⁴	<ul> <li>Adjusted risk of bacterial colonization:</li> <li>Fit-tested and non-fit-tested groups were combined because no significant difference was found between groups</li> <li>N95 compared with medical masks: RR: 0.34; 95% CI: 0.21 – 0.56</li> <li>Medical mask compared to control: RR: 0.67; 95% CI: 0.38 – 1.18</li> <li>Adjusted percent efficacy against 2 or more bacterial infection: <ul> <li>Fit-tested and non-fit-tested groups were combined because no significant difference was found between groups</li> <li>N95 compared with medical masks: 48.2%; 95% CI: 0.0 – 74.4</li> <li>Medical mask compared to control: RR: 18.5%; 95% CI: 0.0 – 58.5</li> </ul> </li> <li>Adjusted percent efficacy against virus and bacteria infection: <ul> <li>Fit-tested and non-fit-tested groups were combined because no significant difference was found between groups</li> <li>N95 compared with medical masks: 33.3%; 95% CI: 0.0 – 75.0</li> <li>Medical mask compared to control: RR: 43.0%; 95% CI: 0.0 – 77.4</li> </ul> </li> </ul>	<ul> <li>"N95 respirators, but not medical masks, were significantly protective against bacterial colonization, co-colonization, viral-bacterial co-infection and dual virus infection in HCWs." – page 4</li> <li>"Although the clinical significance of this finding is unknown in terms of the implications for HCWs, we have shown that such colonization can be prevented by the use of N95 respirators.</li> <li>"In summary, we have described novel data on bacterial infection and co-infections in HCWs, something which has not widely been documented or accepted previously, and shown that N95 respirators consistently provide protection against bacterial colonization and co-infections of the respiratory tract of hospital HCWs." – page 5</li> </ul>

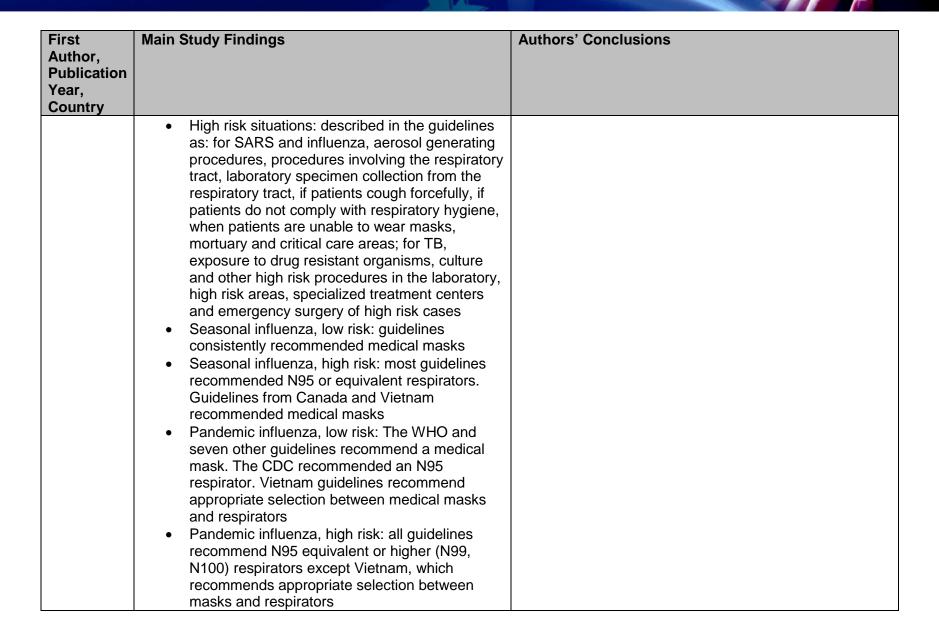
First Author, Publication Year	Main Study Findings	Authors' Conclusions
	<ul> <li>Adjusted percent efficacy against bacterial infection:</li> <li>Fit-tested and non-fit-tested groups were combined because no significant difference was found between groups</li> <li>N95 compared with medical masks: 46.2%; 95% CI: 8.8 – 68.2</li> <li>Medical mask compared to control: RR: 29%; 95% CI: 0.0 – 57.0</li> </ul>	
	<ul> <li>Adjusted percent efficacy against viral infection:</li> <li>Fit-tested and non-fit-tested groups were combined because no significant difference was found between groups</li> <li>N95 compared with medical masks: 48.2%; 95% CI: 0.0 – 75.8</li> <li>Medical mask compared to control: RR: 15.3%; 95% CI: 0.0 – 49.8</li> </ul>	
MacIntyre, 2013, China <sup>12</sup>	<ul> <li>Proportion who developed clinical respiratory illness:</li> <li>Medical mask: 17%</li> <li>Targeted N95 respirator use: 11.8% (p = 0.28 relative to medical mask group)</li> <li>Continuous N95 respirator use: 7.2% (p = 0.024 relative to medical mask group)</li> </ul>	<ul> <li>"In a setting of high occupational risk for HCWs, the key observation of this study is significant protective efficacy against clinical infection of continuous use of N95 respirators compared with targeted use and medical masks, despite significantly poorer adherence in the continuous use N95 arm." – page 963</li> </ul>
	Proportion who developed influenza-like illness  • Medical mask: 0.7%  • Targeted N95 respirator use: 0.4% (p = 0.49 relative to medical mask group)  • Continuous N95 respirator use: 1.0% (p = 0.54 relative to medical mask group)	<ul> <li>"We also showed that the benefit of N95 respirators persisted after adjusting for the potential confounding by influenza vaccination and hand washing." – page 963</li> <li>"However, we were unable to show a difference between the targeted N95 arm and medical mask</li> </ul>

First Author, Publication Year	Main Study Findings	Authors' Conclusions
	Proportion who developed laboratory-confirmed viral respiratory infection in symptomatic subjects:  • Medical mask: 3.3%  • Targeted N95 respirator use: 3.3% (p = 0.99 relative to medical mask group)  • Continuous N95 respirator use: 2.2% (p = 0.44 relative to medical mask group)  Proportion of laboratory-confirmed influenza A or B in symptomatic subjects:  • Medical mask: 0.2%  • Targeted N95 respirator use: 0.4% (p = 0.59 relative to medical mask group)  • Continuous N95 respirator use: 0.5% (p = 0.32 relative to medical mask group)  Proportion of laboratory-confirmed bacterial colonization in symptomatic subjects:  • Medical mask: 21.0%  • Targeted N95 respirator use: 14.5% (p = 0.24 relative to medical mask group)  • Continuous N95 respirator use: 9.0% (p = 0.02 relative to medical mask group)	arm, both reflecting common practice in developed countries, which could indicate equal inefficacy or equal efficacy of a magnitude too small to detect in this trial." – page 963  In summary, this study adds evidence in favor of N95 respirators as respiratory protection for HCWs, and describes for the first time a differential rate of bacterial detection in the respiratory tract depending on level of respiratory protection." – page 965

HCW: healthcare worker; RSV: respiratory syncytial virus; SARS: severe acute respiratory syndrome

Table 4 2	Results of	Included Clinical	<b>Practice Guidelines</b>
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First Author,	Main Study Findings	Authors' Conclusions
Publication		
Year, Country		
	Review of Clinical Practice Guidelines	
Chugati, 2013, Australia <sup>3</sup>	<ul> <li>Guidelines for the use of masks and respirators for HCW, for the prevention of influenza, SARS, and TB:         <ul> <li>A total of guidelines were identified 27</li> </ul> </li> <li>Guidelines were from the CDC, WHO, and from the United Kingdom, Canada, Australia, China, India, Indonesia, Pakistan, Bangladesh, and Vietnam</li> <li>Guidelines reviewed use of masks and respirators for seasonal influenza, pandemic influenza, TB, and SARS</li> </ul>	<ul> <li>"Regardless of the mode of disease transmission, all guidelines recommended the use of respirators while performing high risk procedures on influenza, SARS or TB patients." – page 6</li> <li>"Health care organizations and countries have different policies and guidelines around mask and respirator use for influenza, SARS and TB. These policies not only vary regarding the choice of product used but also the application and specifications. These differences may reflect the relative lack of level-one evidence available to inform policy development." – page 7</li> </ul>
	Consistency/inconsistency between guidelines with reference to the WHO and the CDC guidelines: Situations were divided into two groups:  • Low risk situations: described in the guidelines as: for SARS and influenza, defined as close contact within one meter of the patient, entering the infectious patient's room, clinical care, all patient contact, when infected patient used masks, routine care, in screening areas, during patient transport, before and after patients contact and risk of splashes into face; for TB, defined as sputum microscopy centers, district and subdistrict level hospitals	<ul> <li>"Health organizations and countries should jointly evaluate the available evidence and develop a uniform policy on masks and respirator use in the health care setting." – page 7</li> <li>"There is a need to conduct further studies to generate better evidence to inform policy and current practices. Currently there are major gaps around the modes of transmission of respiratory viruses, the efficacy of cloth masks and the impact of extended and re-use of masks/respirators." – page 7</li> </ul>

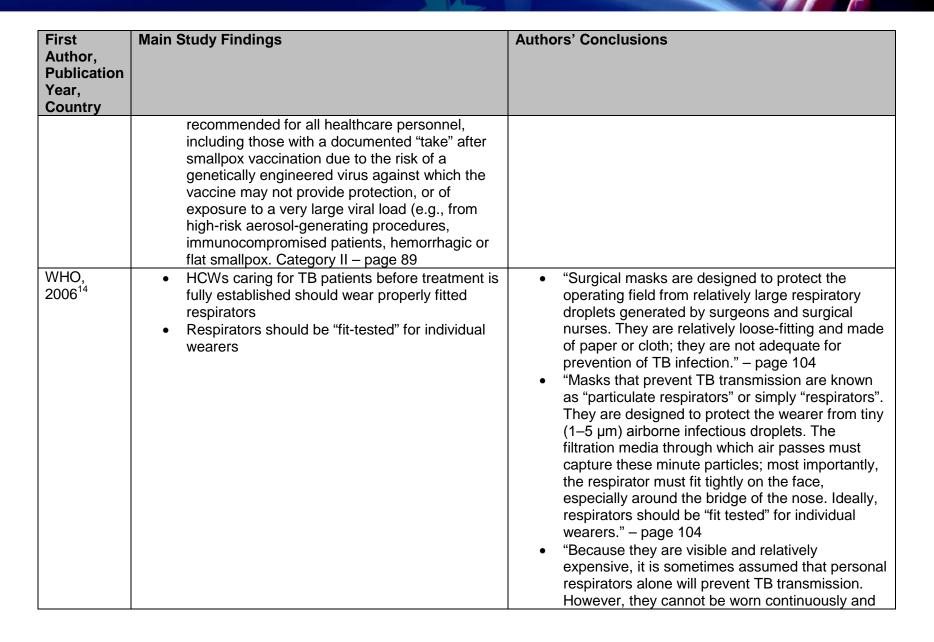


First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
	<ul> <li>SARS low risk: the CDC and 5 other guidelines recommend N95 equivalent respirators, whereas the WHO and guidelines from China recommend medical mask use</li> <li>SARS high risk: all guidelines recommend N95 or higher respirators</li> <li>TB, low risk: all guidelines recommend N95 or equivalent respirators</li> <li>TB, high risk: all guidelines recommend N95 or equivalent respirators</li> </ul>	
Clinical Prac	tice Guidelines	
CDC, 2013, United States	HCWs should wear an N95 or equivalent respirator when involved in aerosol-generating procedures	"HCP should wear respiratory protection equivalent to a fitted N95 filtering facepiece respirator or equivalent N95 respirator (e.g., powered air purifying respirator, elastomeric) during aerosol-generating procedures."
Coia, 2013, United Kingdom	<ul> <li>Medical masks are recommended for:         <ul> <li>Bordatella pertussis until patient has received 5 days of appropriate antibiotic therapy</li> <li>Chlamydia pneumoniae for the duration of acute symptoms until the patient is no longer considered infectious</li> <li>Haemophilus influenzae until the patient has received 24 hours of appropriate antibiotic therapy</li> <li>Influenza virus for the duration of the patient's respiratory symptoms, particularly cough</li> <li>Legionella</li> <li>Mumps virus until patient is no longer infectious</li> </ul> </li> </ul>	<ul> <li>"It is apparent from the recent experiences with severe acute respiratory syndrome and pandemic H1N1 2009 influenza that healthcare workers may have difficulty in choosing the correct type of facial and respiratory protection in any given clinical situation." – page 170</li> <li>"In summary, it should be emphasized from the foregoing that in the majority of situations where respiratory and facial protection is required, a surgical mask is adequate." – page 178</li> <li>"A survey of current UK infection prevention and control policies should be undertaken to establish the degree to which this guidance differs from</li> </ul>

First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
	<ul> <li>Mycoplasma pneumonia for the duration of the patient's symptoms</li> <li>Neisseria meningitides until the patient has received 24 hours of appropriate antibiotic therapy</li> <li>Norovirus, only if there is a risk of spillage or splashing</li> <li>Rubella virus until the patient is no longer infectious</li> <li>Streptococcus pneumonia, but only recommended if there is evidence of ongoing transmission within the healthcare facility – if so, wear mask until patient has received 24 hours of appropriate antibiotic therapy</li> <li>Other viruses, including adenovirus, rhinovirus, non-SARS coronavirus, RSV, wear for the duration of the patient's respiratory symptoms, particularly coughing</li> <li>A filtering face piece 3 mask (equivalent to 98% filtering efficiency) is recommended for:         <ul> <li>Measles virus, worn until the patient is no longer considered infectious</li> <li>Mycobacterium tuberculosis until multi-drugresistant or extensively-drug-resistant tuberculosis is excluded by laboratory testing</li> <li>SARS coronavirus, worn until the patient is no longer infectious</li> </ul> </li> </ul>	what is currently performed, and if possible, establish any source of variation." – page 178

First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
Siegel, 2007, United States <sup>15</sup>	A filtering face piece 3 mask is recommended when performing aerosol generating procedures in patients with:  • Bordatella pertussis • Chlamydia pneumoniae • Haemophilus influenzae • Influenza virus • Measles virus • Mumps virus • Mycobacterium tuberculosis • Mycoplasma pneumoniae • Neisseria meningitides • Rubella virus • SARS coronavirus • Streptococcus pneumoniae • Other respiratory viruses including adenovirus, rhinovirus, non-SARS coronavirus, and RSV • "During aerosol-generating procedures (e.g., bronchoscopy, suctioning of the respiratory tract [if not using in-line suction catheters], endotracheal intubation) in patients who are not suspected of being infected with an agent for which respiratory protection is otherwise recommended (e.g., M. tuberculosis, SARS or hemorrhagic fever viruses), wear one of the following: a face shield that fully covers the front and sides of the face, a mask with attached shield, or a mask and goggles (in addition to	• "In Hong Kong, the use of Droplet and Contact Precautions, which included use of a mask but not a respirator, was effective in protecting healthcare personnel. However, in Toronto, consistent use of an N95 respirator was slightly more protective than a mask. It is noteworthy that there was no transmission of SARS coronavirus to public hospital workers in Vietnam despite inconsistent use of infection control measures, including use of personal protective equipment, which suggests other factors (e.g., severity of

First Author, Publication	Main Study Findings	Authors' Conclusions
Year, Country		
	<ul> <li>gloves and gown)" Category IB – page 80</li> <li>"Don a mask upon entry into the patient room or cubicle" Category IB – page 87</li> <li>"For patients with suspected or proven SARS, avian influenza or pandemic influenza, refer to the following websites for the most current recommendations (www.cdc.gov/ncidod/sars/; www.cdc.gov/flu/avian/; www.pandemicflu.gov/)" – page 87</li> <li>"No recommendation is made regarding the type of personal protective equipment (i.e., surgical mask or respiratory protection with a N95 or higher respirator) to be worn by susceptible healthcare personnel who must have contact with patients with known or suspected measles, chickenpox or disseminated herpes zoster." Unresolved issue – page 89</li> <li>"Wear a fit-tested NIOSH-approved N95 or higher level respirator for respiratory protection when entering the room or home of a patient when the following diseases are suspected or confirmed: Infectious pulmonary or laryngeal tuberculosis or when infectious tuberculosis skin lesions are present and procedures that would aerosolize viable organisms (e.g., irrigation, incision and drainage, whirlpool treatments) are performed Category IB; Smallpox (vaccinated and unvaccinated). Respiratory protection is</li> </ul>	disease, frequency of high risk procedures or events, environmental features) may influence opportunities for transmission." – page 27  • "N95 or higher level respirators may provide added protection for individuals in a room during aerosol-generating procedures." – page 31  • "Although some studies have demonstrated effective prevention of <i>M. tuberculosis</i> transmission in hospitals where surgical masks, instead of respirators, were used in conjunction with other administrative and engineering controls, CDC currently recommends N95 or higher level respirators for personnel exposed to patients with suspected or confirmed tuberculosis. Currently this is also true for other diseases that could be transmitted through the airborne route, including SARS and smallpox until inhalational transmission is better defined or healthcare-specific protective equipment more suitable for preventing infection are developed. Respirators are also currently recommended to be worn during the performance of aerosol-generating procedures (e.g., intubation, bronchoscopy, suctioning) on patients with SARS coronavirus infection, avian influenza and pandemic influenza." – page 54



First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
		are likely not to be in use when unsuspected TB cases, or unsuspected MDR-TB, are encountered. For these reasons, administrative controls that aim to detect and separate cases, and engineering controls that can reduce the risk even for unsuspected cases, are more important." – page 104

CDC: Centers for Disease Control; HCW – healthcare worker; NIOSH: National Institute for Occupational Safety and Heath; SARS: severe acute respiratory syndrome; TB: tuberculosis; WHO: World Health Organization